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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,074	02/15/2002	Matthew C. Coffey	032775-091	8498

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,074	COFFEY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 06/17/2004 09/13/2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 13, filed 08/17/04. Claims 1, 4, 12, 19, 26, 30 have been amended. Claims 1-34 are pending. Claims 31-34 are withdrawn from the consideration. Claims 1-30 are considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-5, 8-11, 12-25, 26-28 and 30 are still provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-22 of copending Application No. 10,602,024.

5. Applicants traverse the rejection and submit that the conflict claim 16 of "024" application requires an ex vivo step of using reovirus to identify a group of cells as ras-activated neoplasm, then a second step comprises treatment of the ras-activated neoplasm with a reovirus

and a therapeutic agent. In contrast, amended claim 1 of the present application involves administering reovirus to ras-activated neoplastic cells to increase their sensitivity to a chemotherapeutic agent. There is no suggestion or motivation either in the claims of the "024 application" or in the knowledge generally available to one of ordinary skill in the art to modify claim 16 of the "024' application to arrive at the invention claimed herein. Specifically, claims of the "024 application" do not teach or suggest increasing the sensitivity of cells to chemotherapeutic agents by using reovirus. Nor do the claims of "the 024 application" provide a reasonable expectation of success that reovirus can be used to increase the sensitivity of ras-activated neoplastic cells to therapeutic agents. Therefore, the application "024' does not teach each and every limitation of the rejected claims.

6. Applicants' argument has been respectfully considered; however, it is not found persuasive because the limitation of increasing a sensitivity of ras-activated neoplasm cell to the chemotherapeutic agent by using reovirus is only a purpose or intended use of claimed method. Applicants are reminded that this is considered only as a preamble language. Applicants are directed to the case law of Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). In the instant case, a preamble language of increasing the sensitivity of a chemotherapeutic agent merely expresses a purpose and intended result, and as such is non-limiting since the language does not result in manipulative difference in steps of claims. Nevertheless, the conflict claims in application "024" include the steps of using the reovirus and a chemotherapeutic agent to treat a ras-mediated neoplasm. As it is well known in the art that only Ras-mutated and activated cell line contains an altered PKR pathway, and enables the reovirus to replicate and oncolyze the tumor cell, it would have been obvious for a person with ordinary skill in the art to directly use the reovirus to oncolyze the ras mutation neoplasm without an ex vivo a ras mutation test absence unexpected result. Thus, the rejection is maintained.

7. Claims 1-6, 8-11, 12-13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26-28 are still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 11-18, 22, 23, 25, 26, 27, 28, 32, 33-34 of U.S. Patent No. 6,565,831B1 on the same ground as stated in the previous Office Action.

8. Applicants traverse the rejection and submit that the conflict claims does not teach or suggest that reovirus increases the sensitivity of ras-activated cells to chemotherapeutic agents. Furthermore, there is no motivation or suggestion to modify the claims of the 831 patent to arrive at the presently claims.

9. Applicants' argument has been respectfully considered; however, it is not found persuasive because the limitation of increasing a sensitivity of ras-activated neoplasm cell to the chemotherapeutic agent by using reovirus is only a purpose or intended use of claimed method as discussed above. The limitation of increase sensitivity of ras-activated neoplasm cell to a chemotherapeutic agent does not appear to change the manipulative steps of using reovirus together with a chemotherapeutic agent for treating a ras-activated neoplasm compared with that of conflict claims. The claimed method is still anticipated by the claims. The rejection is therefore, maintained.

10. Claims 1-6, 8-11, 12-13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-8,13-20, 24-33 and 34 of U.S. Patent No. 6,136,307A on the same ground as stated in the previous Office Action.

11. Applicants traverse the rejection and assert that the conflict claims in patent "307" do not teach or suggest that reovirus increases the sensitivity of ras-activated cells to chemotherapeutic agents, that reovirus can render ras-activate and that reovirus prevents the development of drug resistance to a chemotherapeutic agent in ras-activated neoplastic cells. Therefore, the claimed invention is not obvious in view of the claims of 307 patent.

12. Applicants' argument has been respectfully considered; however, it is not found persuasive because the limitation of increasing a sensitivity of ras-activated neoplasm cell to the chemotherapeutic agent by using reovirus is only a purpose or intended use of claimed method, which does not result in manipulative difference in steps of claims as discussed above. The claimed method is still anticipated by the claims. The rejection is therefore, maintained.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1, 2, 3, 4, 5, 6, 8, 9, 12-14, 17-23, 26-28 are still rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al. (US Patent No. 6,136,307A) or Lee et al. (WO 00/50051A2) on the same ground as stated in the previous Office Action.

15. Applicants argue that neither "307 patent" nor "WO 51A2" specifically teaches a method of sensitizing a ras-activated neoplastic cell to a chemotherapeutic agent (claim 1). Therefore, either reference fails to teach each and every element of the claimed invention.

16. Applicants' argument has been respectfully considered; however, it is not found persuasive because the limitation of increasing a sensitivity of ras-activated neoplasm cell to the chemotherapeutic agent by using reovirus is only considered as a purpose or intended use of claimed method, it does not result in manipulative difference in steps of claims. Therefore, the claimed method is still anticipated by the conflict claims. Therefore, the rejection is therefore, maintained.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1, 2, 3, 4, 5, 6-9, 12-14, 17-23, 26-28 are still rejected under 35 U.S.C. 102(b) as being anticipated by Robert et al. (WO 99,18799A1) on the same ground as stated in the previous Office Action.

19. Applicants traverse the rejection and argue that Roberts does not teach each and every element of the claimed invention. Especially, the limitation of sensitizing a ras-activated neoplastic cell to a chemotherapeutic agent using reovirus is not taught or suggested by the cited reference. Therefore, claim 1 and its dependent claims 2-6, 8 or 9 are not anticipated by this reference.

20. Applicants' argument has been fully considered; however, it is not found persuasive because the recitation of increasing a sensitivity of a chemotherapeutic agent is only considered as a purpose or intended use of claimed method, which does not result in manipulative difference in steps of claims as discussed above. Moreover, the tumor or cancer cell line that Robert et al taught comprises a mutated oncogenic ras, such as non-small cell lung cancer in view of disclosure of Zhang et al. (Gene Ther. 2000, Vol. 7, pp. 2000-2050), and UM7MG cancer cell line in view of the disclosure by Prigen et al. (J. Biologic. Chemistr. 1996, Vol. 271, No. 41, pp. 25635-25645), the reference by Robert et al. inherently anticipates the rejected claims. The rejection is then maintained.

21. (The examiner apologized that claim 7 is inadvertently missed in the previous office Action and it should be included because the previous Office Action points out that Robert et al. use reovirus plus interferon for treating tumor. Please see lines 32-33 of previous Office Action).

Conclusion

No claims are allowed.

22. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
11/02/2004